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06/01/2001

Adilson Leite

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FULBRIGHT & JAWORSKI, LLP
666 FIFTH AVE
NEW YORK, NY 10103-3198

EXAMINER

SRIVASTAVA, KAILASH C

ART UNIT

PAPER NUMBER

1657

MAIL DATE

DELIVERY MODE

05/01/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--|-------------------------------------|--|
| Office Action Summary | Application No. 09/870,498 | Applicant(s) LEITE ET AL. | |
| | Examiner Dr. Kailash C. Srivastava | Art Unit 1657 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 17-28 and 31 is/are pending in the application.
- 4a) Of the above claim(s) 1-4 and 17-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5 and 7 is/are rejected.
- 7) ☒ Claim(s) 6 and 31 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Response and amendment filed 06 31 January 2008 in response to Office Action mailed 31 October 2007 is acknowledged and entered. The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office action.

Informal Matters

2. Examiner very much appreciates that in response filed 31 January 2008, applicants have provided critical and pertinent application data in the header of each of the response pages including pages with Amended Claims. This information is extremely useful in keeping applicants response papers together after those papers are separated for different codings at the USPTO.

3. Regarding the interview conducted on 06 February 2007, the summary states that it was agreed to withdraw the written description rejection to Claims 5-7 and 29 under 35 U.S.C. §112, first paragraph and Obviousness rejection to Claims 5-7 and 29 under 35 U.S.C. § 103 (a). There is no statement of agreement to allow the application. The box "N/A" was checked because full agreement was not achieved, only partial. As the applicants have acknowledged in their response filed 08 August 2007, in the subsequent Office Action, the rejections under 35 U.S.C. §112 and §103 were withdrawn.

Withdrawals of Rejection based on Applicant's Amendments and Remarks

4. In view of remarks and amendments filed 31 January 2008, the following objections and rejections in the Office Action mailed 31 October 2007 are hereby withdrawn:

- Anticipatory rejection of Claim 5 under 35 U.S.C. §102 (b) as anticipated by Travis et al (US Patent 5,447,914);
- Anticipatory rejection of Claims 5-6 and 30 under 35 U.S.C. §102 (b) as anticipated by Little et al. (WO 00/18951) with evidence provided by Charles S. Gasser (1996, U. C. Davis, Biological Sciences, Amino Acid Properties. Printed from http://www.mcb.ucdavis.edu/courses/bis_102/AAProp.html on 25 October 2007); and

- Obviousness rejection of Claims 5-7 and 30 under 35 U.S.C. § 103 (a) as obvious over combined teachings from Travis et al (US Patent 5,447,914) in view of Little et al. (WO 00/18951) with evidence provided by Charles S. Gasser (1996, U. C. Davis, Biological Sciences, Amino Acid Properties. Printed from <http://www.mcb.ucdavis.edu/courses/bis102/AAProp.html> on 25 October 2007) and further in view of Aley et al (Infection and Immunity, 1994, Volume 62, pages 5397-5403).

Claim Status

5. Claim 31 has currently been added.
6. Claims 8-16 and 29-30 have been cancelled.
7. Claim 5 has currently been amended.
8. Claims 1-7, 17-28 and 31 are pending.
9. Claims 1-4 and 17-28 have been withdrawn.
10. Claims 5-7 and newly presented Claim 31 are examined on merits.

Claim Rejections - 35 U.S.C. §112, First Paragraph

11. Claims 5 and 7 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Claims 5 and 7 are rejected under 35 U.S.C. §112, first paragraph as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with those claims.

In the instant case, the claims as presented in the amendments filed 06 August 2007 are drawn to the genus of an isolated antimicrobial peptide consisting of from 10 to about 50 amino acids, wherein said peptide genus comprises 10 to about 12 continuous amino acids, wherein a given number of those

contiguous amino acids are hydrophobic residues, at least one a histidine, glutamic acid or serine with the proviso that two of the hydrophobic amino acids are adjacent tryptophans.

Figure 1 as currently presented shows and the description thereof discusses 14 different peptides. However, only sequences 1-4 meet the criteria of “10 to about 50 amino acids” because each of the other 10 sequences show only 7 amino acids. Please note that aside from the above mentioned requirement, said 10 sequences also do not meet all the criteria mentioned in Claim 5. Furthermore, on the basis of currently presented description in specification, applicants have not provided sufficient description to obtain said sequences with the claimed antimicrobial activity. That is, applicants are in possession of the broad genus (i.e., the sequences, because the claimed sequences can also be obtained through computer modeling). However, in the presently described specification applicants have not shown how to obtain said sequences with the subset of claimed functionality (i.e., antimicrobial activity) as is claimed in Claims 5 and 7. Accordingly, they lack possession of the specifically claimed subset.

Applicants’ arguments cited *supra* have been fully and carefully considered, but are not persuasive for the reasons of record at Pages 2-3, item 11 of the Office Action mailed 31 October 2007 and further because of the reasons explained in the preceding paragraph. Furthermore, applicants have not pointed out where in the specification (i.e., Pages, paragraphs, Lines) said information is present to persuade the Examiner that the applicants are indeed in the possession of Claimed invention and that the claimed invention is commensurate in scope with Claims. Accordingly, the rejection of Claims is maintained and adhered to.

Claim Rejections - 35 USC § 102

12. Claims 5 and 7 are rejected under 35 U.S.C. §102(b) as anticipated by Hancock et al (US Patent 6,040,435).

Claim 5 recites an isolated antimicrobial peptide consisting of from 10 to about 50 amino acids, wherein said peptide genus comprises 10 to about 12 contiguous amino acids, wherein a given number of those contiguous amino acids are hydrophobic residues, at least one a histidine, glutamic acid or serine with the proviso that two of the hydrophobic amino acids are adjacent tryptophans.

Regarding Claim 5, Hancock et al. teach a peptide comprising 20 amino acids. Said peptide comprises 10-12 contiguous amino acids, wherein at least 7 of those amino acids are hydrophobic, at least

3 are basic, at least one is serine and two of hydrophobic amino acids are tryptophan adjacent to each other (See Column 11, Lines 34-55 and illustration below).

NH₂—KK **WWRRVLSGLKTG** PALSNV-COOH, (20 amino acid residues)

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|----|----|----|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
| | h | h | | | h | h | h | h | | | h |
| | | | b | b | | | | | | b | |

Above illustration, as an example indicates a total of 20 amino acid residues. Among 12 of said contiguous amino acid residues, 7 are hydrophobic (indicated by h), 3 basic (indicated by b), at least one serine (indicated by S) and two adjacent tryptophan (indicated by W).

Other examples are shown below.

NH₂—KK**WWRRVLKGLSSG** PALSNV-COOH,

NH₂—KK**WWRRALQALKNG** PALSNV-COOH,

NH₂—KK**WWRRVLSGLKTA** GPAIQSVLNK-COOH,

NH₂—KK **WWRRALQGLKTA** GPAIQSVLNK-COOH,

NH₂—KK **WWKAQKAVNSGP** NALQTLAQ-COOH,

NH₂—KK **WWKAKKFANS GP** NALQTLAQ-COOH,

NH₂—KK **WWKFIKKAVNSG** TTGLQTLAS-COOH,

Hancock et al., further teach, isolated antimicrobial peptides of at least 20-30 amino acid length (Column 5, Lines 33-34) analogs derivatives and conservative variations of said peptides having hydrophobic substitutions (Column 4, Lines 29-34; Lines 58-63) and thus said peptides inherently are amidated, carboxymethylated, or cyclized (amidation of the dodecamer can be the remaining peptide fused to the C-terminus; in the example above, it is PALSNV-COOH).

Thus, Hancock et al. teach an isolated antimicrobial peptide (See abstract) having each of the limitations that the instant Claims 5 and 7 have. Therefore, the prior art isolated antimicrobial peptide is comprised of the same amino acid constituents as are instantly claimed (See e.g., *In re Best*, 195 USPQ 430, 433-CCPA 1977).

Therefore, the reference is deemed to anticipate the cited claim.

Conclusion

13. Claims 6 and 31 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. For aforementioned reasons, no Claims are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached at (571)-272-0925 Monday through Thursday 7:30 A.M. to 6:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Dr. Kailash C Srivastava/
Examiner, Art Unit 1657

Kailash C. Srivastava, Ph.D.
Patent Examiner
Art Unit 1657
(571) 272-0923

April 30, 2008

/Jon P Weber/
Supervisory Patent Examiner, Art Unit 1657